

White paper on repackaging
By the Montana Board of Pharmacy

The Board of Pharmacy receives frequent questions regarding the legality of repackaging medications into unit dose daypacks for use in long-term care facilities. In some cases, the medications have been sent to the long-term care facility in standard outpatient vials by a mail order pharmacy, further confusing the issue. The local pharmacy under contract with the long-term care facility is then asked to repackage the medication for use.

207.10 CFR, Exemptions for domestic establishments, states that "Pharmacies that operate under applicable local laws regulating dispensing of prescription drugs and that do not manufacture or process drugs for sale other than in the regular course of the practice of the profession of pharmacy, including dispensing and selling drugs at retail" are not required to be registered, and that "registration is not necessary for the protection of the public health".

When a pharmacy is asked to repackage bulk prescription medications that have been dispensed to a patient of a long-term care facility for that patient's use, the pharmacy violates no rule or statute when it repackages these medications into unit dose daypacks for convenience and accuracy of administration, provided that the medication can be positively identified and is properly labeled, including lot number and expiration date. The repackaged unit dose daypack must be properly labeled as well, including the name, address and phone number of the dispenser(s), name of prescriber, name of patient, name and strength of the drug, directions for use and the date of filling. The lot number, expiration date and date of repackaging must also be specified. The expiration date of the repackaged product must be stated as the actual expiration date listed on the vial, or one year from the date of repackaging, whichever is less. If the lot number and expiration date are not given on the original patient vial, or if the repackaging pharmacist cannot positively identify the medication, repackaging must not take place.